

AF-



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,808	07/27/2001	Mark John Gibbs	10338-2U1 (2441651/VPA)	2166
570 7590 12/23/2005 AKIN GUMP STRAUSS HAUER & FELD L.L.P. ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103			EXAMINER FORMAN, BETTY J	
			ART UNIT 1634	PAPER NUMBER

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/916,808	<b>Applicant(s)</b> GIBBS ET AL.	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 September 2005 has been entered.

### ***Status of the Claims***

2. This action is in response to papers filed 14 September 2005 in which claims 1 and 34 were amended and claims 10-33 were canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 14 March 2005 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-9 and 34 are under prosecution.

### ***Specification***

3. The disclosure is objected to because it contains (at ¶ 151) an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

**First paragraph of 35 U.S.C. 112: Written Description**

4. Claims 1-9 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a set of promiscuous probes wherein a predetermined combination of the probes detects and discriminates target polynucleotides and the number of probes in the predetermined combination is less than the number of detected and distinguished targets.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement*; Federal Register/ Vol. 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

**Reduction to practice**

The specification does not describe an actual reduction to practice of the claimed invention. The specification teaches methods and computer programs for selecting targets and probes. The specification further illustrate a single and partial example of the claimed probe combination (Fig. 7). The claimed probe sets encompasses an enormous number probe combinations. However, the specification does not describe an actual reduction to practice of the claimed probe sets.

**Completed by drawings**

The specification does not teach that the invention is complete as evidenced by drawings. The drawings of the specification illustrate the method of over-lapping hybridizations (Fig. 2). The drawings also illustrate methods for probe and target selection (Fig. 10) and "hypothetical micro-array" (Fig. 8). The drawings do not provide evidence that the invention is complete because the drawings do not provide or complete the description of the promiscuous probe sets and probe set combinations.

**Description of identifying characteristics**

The specification has not been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention.

The specification provides guidance for selecting targets and probes for their detection. The specification describes the methods of probe selection. However, the instant claims are drawn to probe sets. The specification does not describe the probe sets in terms of distinguishing characteristics.

the specification does not teach or describe identifying characteristics which show that applicant was in possession of the claimed probe sets. Therefore, the specification does not provide a written description of the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The courts have stated that the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonable conclude **the inventor had possession** of the claimed invention see *In re Vas-Cath, Inc.* 935F2d. 1555, 1563, 19 USPQ2d 1111,1116.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3, 4, 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Portugal (U.S. Patent No. 6,727,061, filed 2 February 1998).

Regarding Claim 1, Portugal discloses an array (dot blot or solid surface, Column 6, lines 4-7) comprising a set of promiscuous probes for detecting and discriminating 4 target polynucleotides at individual addresses (applied to DNA blots, Column 7, lines 5-10), wherein the number of probes (i.e. 4) is less than the number of targets (i.e. 5) and wherein a predetermined combination of the probes detects and discriminates the targets (Fig. 3 and Column 5, line 53-Column 6, line 341).

Regarding Claim 3, Portugal discloses the array wherein at least one probe is non-promiscuous and hybridizes to a unique target (i.e. at 62 °C, SEQ ID NO: 2 only hybridizes to *S. dysenteriae*, Table 3).

Regarding Claim 4, Portugal discloses the array wherein at least one probe is a pivot that divides two distinct groups (i.e. SEQ ID NO: 3 @ 70 °C divides *Shigella*/ *Escherichia*, Table 4).

Regarding Claim 6, Portugal discloses the probes immobilized on a solid support (Column 6, lines 4-7).

Art Unit: 1634

***Claim Rejections - 35 USC § 102/103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-6 and 34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lane et al (U.S. Patent No. 5,401,631, issued 28 March 1995).

Regarding Claims 1-2 and 34, Lane et al disclose an array (e.g. membrane, Column 9, lines 57-65) comprising a set of promiscuous probes for detecting and discriminating target polynucleotides at individual addresses (e.g. DNA blots, Column 7, lines 5-10), wherein the number of probes (i.e. 41, Column 7, line 1-Column 9, line 53) is less than the number of targets (i.e. 139, Tables 3, 4, 5) and wherein a predetermined combination of the probes detects and discriminates the targets (Column 11, lines 44-64).

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Lane et al is silent with regard to probe combinations whereby the combination discriminates the target from other targets. However, the combinations recited in Claims 1-9 and 34 is deemed to be inherent in the distinguishing probes of Lane et al because the reference teaches the probes having distinguishing abilities (tables 3-5). The claimed probe combinations defines an intended use for the probes whereby targets are distinguished. The combinations do not structurally define the probes over the probes taught by Lane et al.

Alternatively, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the probes of Lane et al into set combinations for

Art Unit: 1634

target discrimination. One of ordinary skill in the art would have been motivated to do so based Lane's suggestion to do so )Column 11, line 44-Column 12, line 2).

The burden is on applicant to show that the claimed (property X) is either different or non-obvious over that of Lane et al.

Regarding Claim 3, Lane et al disclose the probe wherein one hybridizes to a unique target e.g. *Borrelia Spirochetes* (Column 14, lines 1-4).

Regarding Claim 4, Lane et al disclose the probes wherein at least one hybridized to a pivot sequence dividing eubacteria vs non-eubacteria and gram positive vs gram negative (Column 11, lines 44-64).

Regarding Claim 5, Lane et al disclose the probes wherein at least one hybridizes to a redundant target (Column 13, lines 16-28).

Regarding Claim 6, Lane et al disclose the probes immobilized to a solid support (Column 9, lines 57-66).

9. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane et al (U.S. Patent No. 5,401,631, issued 28 March 1995) in view of Hogan (U.S. Patent No. 6,821,770, filed 3 May 2000).

Regarding Claims 7-8, Lane et al disclose an array (e.g. membrane, Column 9, lines 57-65) comprising a set of promiscuous probes for detecting and discriminating target polynucleotides at individual addresses (e.g. DNA blots, Column 7, lines 5-10), wherein the number of probes (i.e. 41, Column 7, line 1-Column 9, line 53) is less than the number of targets (i.e. 139, Tables 3, 4, 5) and wherein a predetermined combination of the probes detects and discriminates the targets (Column 11, lines 44-64). Lane teaches the probes are immobilized (Column 9, lines 57-66) but they do not teach arrayed nucleic acids. However,



Art Unit: 1634

high density arrays of probe sets were well known in the art at the time the claimed invention was made as taught by Hogan. Hogan teaches a similar array of probe wherein a set of probes detects and discriminates a target wherein the probes are immobilized in a high-density array whereby the arrayed probes do not mingle with other probes and hybridization provides discrete information about the test sample (Column 10, lines 45-54). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the immobilized probes of Hogan by immobilizing the probes in a high density array as taught by Hogan. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing discrete information about the test sample as taught by Hogan (Column 10, lines 45-54).

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (U.S. Patent No. 6,821,770, filed 3 May 2000) Lockhart et al (6,329,140, issued 11 December 2001).

Regarding Claim 9, Lane et al disclose an array (e.g. membrane, Column 9, lines 57-65) comprising a set of promiscuous probes for detecting and discriminating target polynucleotides at individual addresses (e.g. DNA blots, Column 7, lines 5-10), wherein the number of probes (i.e. 41, Column 7, line 1-Column 9, line 53) is less than the number of targets (i.e. 139, Tables 3, 4, 5) and wherein a predetermined combination of the probes detects and discriminates the targets (Column 11, lines 44-64). Lane teaches the probes are immobilized (Column 9, lines 57-66) but they do not teach the probes are immobilized via a spacer.

However, probes linked to a solid support via a spacer were well known in the art at the time the claimed invention was made as taught by Lockhart et al who teach the preferred immobilization of probe includes attaching probes to a high density array via a spacer i.e. linker (Column 22, lines 11-35) wherein their arrays are especially useful for distinguishing

Art Unit: 1634

between mycobacterium species (Column 12, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Lane et al by immobilizing the probes on a high-density array via a spacer as taught by Lockhart et al based on Lockhart's expressed suggestion to do so (Column 12, lines 1-5).

### ***Double Patenting***

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claims 1-9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of copending Application No. 10/343,170. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### **Comments**

13. Applicant's proposal to cancel Claims 1-9 of copending application 10/343,107 upon indication that the instant claims are otherwise in condition for allowance is acknowledged. The rejection is maintained.

### **Conclusion**

Art Unit: 1634

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

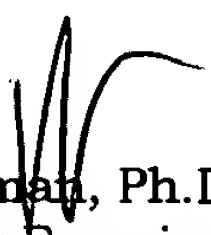
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
December 15, 2005